

K011197

1/2

DEC 14 2001

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the DermaClear UV-B Phototherapy System is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant:	Coherent Star
Address:	1249 Quarry Lane, Suite 100 Pleasanton, CA 94566
Contact Person:	C. Robert Payne, Jr., P.E.
Telephone:	(925) 249-8031
Fax:	(925) 249-8010
Preparation Date:	April 13, 2001
Device Trade Name:	DermaClear UV-B Phototherapy System
Common Name:	Localized, narrow band ultraviolet phototherapy equipment
Classification Name:	Ultraviolet lamp for dermatologic/ skin disorders (see 21 CFR 878.4630).
Legally Marketed Predicate Devices:	Avex Industries, LTD., PhotoTherapeutiX Model 1600B (K935526); Daavlin Co., Psorawand™ (Psoralite; K930856) National Biological Corp., HandiSol™ Phototherapy Device (K924077), Panosol II™ Phototherapy Device (K904427); PhotoMedex, the parent of AccuLase, Inc., XTRAC™ Excimer Laser Phototherapy System, AL7000 (K992914, K003705); SurgiLight, Inc. EX-308 (K993328).

K011197 2/2

System Description:

The DermaClear UV-B Phototherapy System is an ultraviolet light source and energy delivery system. The light source is contained within a protective console. The complete system also includes a handpiece connected to the console via an umbilical. Time and dosing parameters and an interface to other system features are controlled from a display panel on the console. The delivery system allows UV-B light to pass through the handpiece to selectively treat skin and nail lesions without exposure to the healthy skin.

Intended Use of the Device:

The DermaClear UV-B Phototherapy System is a medical ultraviolet light source and delivery device intended for the treatment of psoriasis and vitiligo. The DermaClear UV-B Phototherapy System is intended for use on all skin types (I – VI).

Performance Data:

None. The technological specifications of the DermaClear UV-B Phototherapy System are the same or very similar to those of the claimed predicate devices. The DermaClear UV-B Phototherapy System has the same indications for use for which the claimed predicates have been cleared. Therefore, performance data is not required.

Conclusion:

Based on the foregoing, the DermaClear UV-B Phototherapy System is substantially equivalent to the legally marketed, claimed predicate devices for the purposes of this 510(k) submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. C. Robert Payne, Jr., P.E.
Director of Regulatory Affairs
and Quality Assurance
Lumenis
1249 Quarry Lane, Suite 100
Pleasanton, California 94566

DEC 14 2001

Re: K011197

Trade/Device Name: DermaClear UV-B Phototherapy System
Regulation Number: 878.4630
Regulation Name: Ultraviolet lamp for dermatological disorders
Regulatory Class: II
Product Code: FTC
Dated: September 26, 2001
Received: October 1, 2001

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

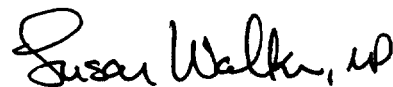
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. C. Robert Payne, Jr., P.E.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K 011197

Device Name: DermaClear UV-B Phototherapy System

Indications for Use:

The DermaClear UV-B Phototherapy System is a medical ultraviolet lamp and delivery device intended for the treatment of psoriasis and vitiligo. The DermaClear UV-B Phototherapy System is intended for use on all skin types (I – VI).

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR
(per 21 CFR 801.109)

Over-the-Counter Use ☐

Susan Walk
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 011197